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#36

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,735,621

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,735,621 issued April 5, 1988, which claims the medical device REALITY Female Condom, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 762 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of June 14, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (1,460 - 157) + 557 \\ &= 1,209 \text{ days}\end{aligned}$$

Since the regulatory review period began October 31, 1987, before the patent issued (April 5, 1988), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 31, 1987 to April 5, 1988 is 157 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1,460 - 157 = 1,307$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product May 7, 1993 when added to the period of extension calculated above (1,209 days) cannot exceed fourteen years. The period of extension is thus limited to May 7, 2007, by operation of 35 U.S.C. § 156(c)(3). Since the original patent term of seventeen years (35 U.S.C. § 154) would expire on April 5, 2005, the period of extension is the number of days to extend the term of the patent from its expiration date to and including May 7, 2007, or 762 days.

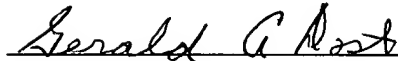
The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. It is noted that applicant has filed another application for patent term extension for U.S. Patent No. 4,976,273 which is also based upon the regulatory review of the product REALITY Female Condom. No more than one patent may be extended for a regulatory review period of a product. 35 U.S.C. 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted and a certificate of extension will be issued to U.S. Patent No. 4,735,621. Accordingly, the application for patent term extension of the patent having the later date of issuance will be denied. In the absence of such request for reconsideration or an election of the other patent, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,735,621 a certificate of extension, under seal, for a period of 762 days.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,735,621
Granted:	April 5, 1988
Applicant:	Lasse Hessel et al.
Owner of Record:	Chartex International Plc.
Title:	TUBULAR PROTECTIVE DEVICE FOR PROTECTION AGAINST TRANSFER OF INFECTIOUS MATTER DURING SEXUAL INTERCOURSE
Classification:	604/349
Product Trade Name:	REALITY

Term Extended: 762 days



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cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: REALITY
FDA Docket No.: 93E-0290